UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RICHARD WISNIEWSKI and
LEONIDAS C. LEONARD

Appeal 2006-3326
Application 09/881,909
Technology Center 3700

Decided: April 30, 2007

Before EDWARD C. KIMLIN, BRADLEY R. GARRIS, and CHUNG K. PAK, *Administrative Patent Judges.*

KIMLIN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal from the final rejection of claims 1-55. Claim 1 is illustrative:

1. A thermal transfer system, comprising:

a container for receiving a medium;

a structure positioned in the container such that the structure segments the container into a plurality of compartments wherein a distal end of the structure is in close proximity to an interior surface of the container to allow formation of a thermal transfer bridge, by said medium, wherein heat is transferred from said distal end of the structure through said thermal bridge to said interior wall in response to said interior wall being actively cooled.

The Examiner relies upon the following references in the rejection of the appealed claims:

Voorhees	US 983,466	Feb. 7, 1911
Morrison	US 1,874,578	Aug. 30, 1932
West	US 2,114,642	Apr. 19, 1938
Finnegan	US 2,129,572	Sep. 6, 1938
Brown	US 2,391,876	Jan. 1, 1946
Gross	US 2,915,292	Dec. 1, 1959
Burroughs	US 3,318,105	May 9, 1967
Euwema	US 3,550,393	Dec. 29, 1970
Nakao (as translated)	JP 57-58087	Apr. 7, 1982

Kalhori, "Studies on Heat Transfer From a Vertical Cylinder, With or Without Fins, Embedded in a Solid Phase Change Medium," *Transactions of the ASME, Journal of Heat Transfer,* Vol. 107, 44-51 (Feb. 1985).

Nagashio (as translated)	JP 3-43390	Feb. 25, 1991

Wisniewski, "Large-Scale Freezing and Thawing of Biopharmaceutical Drug Product," *Proceedings of the International Congress*, Advanced Technologies For Manufacturing of Aseptic & Terminally Sterilized Pharmaceuticals & Biopharmaceuticals, 132-139 (Feb. 1992).

Koerber	JP 06064094 A	Mar. 8, 1994
Cothern	US 5,535,598	Jul. 16, 1996

Appellants' claimed invention is directed to a thermal transfer system comprising a container that receives a medium, a structure within the

container which segments the container into a plurality of compartment and whose distal end is in close proximity to the interior surface of the container, such that heat is transferred from the distal end of the structure through a thermal bridge to the interior wall of the container in response to the wall being actively cooled.

Appealed claims 1-5, 7-10, 12-34, 36, 37, and 39-55 stand rejected under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Wisniewski. In addition, the appealed claims stand rejected under 35 U.S.C. § 103(a) as follows:

(a) claims 1-5, 7-10, 12-34, 36, 37, and 39-55 over Wisniewski in view of Kalhori,

(b) claims 1-5, 7-10, 12-34, 36, 37, and 39-55over the combination of Wisniewski and Kalhori further in view of Euwema, Cothern, West, Morrison, and Nakao,

(c) claims 1-5, 7-10, 12-34, 36, 37, and 39-55over the prior art cited above in view of admitted prior art in the Specification,

(d) claims 11 and 38 over the prior art cited above further in view of Brown or Gross, and

(e) claims 6 and 35 over the prior art cited above further in view of Nagashio or Koerber.

Appellants present separate arguments only for claims 11 and 38. Accordingly, the remaining claims on appeal stand or fall together.

We have thoroughly reviewed each of Appellants' arguments for patentability, as well as the declaration evidence relied upon in support thereof. However, we find that the Examiner's rejections are supported by

the prior art evidence and in accord with current patent jurisprudence. Accordingly, we will sustain the Examiner's rejections for the reasons set forth in the Answer, which we incorporate herein, and we add the following for emphasis only.

We consider first the Examiner's rejection of claims 1-5, 7-10, 12-34, 36, 37, and 39-55 under § 102/§ 103 over Wisniewski. There is no dispute that Wisniewski, like Appellants, discloses a thermal transfer system comprising the presently claimed container for receiving a medium, a structure position in the container that segments the container into a plurality of compartments and which has a distal end that extends toward the interior of the container, wherein heat is transferred from the distal end of the structure toward the interior wall of the container in response to the interior wall being actively cooled. The dispositive issue on appeal is whether the distal end of the structure within the container is in *close proximity* to the interior surface of the container such that heat is transferred from the distal end through a *thermal transfer bridge* located between the distal end and the interior wall of the container. It is Appellants' principal contention that the thermal transfer system of Wisniewski does not result in the formation of a thermal transfer bridge between the structure and the interior wall of the container. On the other hand, the Examiner has placed on the record a detailed analysis of the Wisniewski system which purportedly demonstrates that the formation of the claimed thermal transfer bridge is inherent in the Wisniewski system. Appellants rely upon two declarations of Wisniewski, who is one of the authors of the Wisniewski prior art article, as well as one

of the present inventors, as evidence that a thermal transfer bridge is not formed in the Wisniewski system of the prior art.

Upon thorough review of Appellants' arguments and declaration evidence, as well as the Examiner's Answer, we find that the Examiner has established a prima facie case of inherency sufficient to shift to Appellants the burden of establishing that the Wisniewski system does not, in fact, allow for the formation of a thermal transfer bridge. In our view, Appellants have not met their burden.

The Examiner sets forth a reasonable analysis of heat transfer in the Wisniewski system at page 15 of the Final Rejection, which is incorporated by reference into the Answer. To wit, the Examiner explains that cold silicon oil is first pumped to the jacket of the Wisniewski vessel, which cools the medium in the tank to the coolest temperature that the coolant oil is capable of effecting. The coolant oil of the system achieves a higher temperature during this heat transfer with the medium and is then piped to the central cooling structure having fins corresponding to Appellants' cooling structure. The heated cooling oil also cools the medium in the central portion of the tank that is in communication with the structure, but the medium in the central portion of the tank will always be at a higher temperature than the medium near the wall of the tank that received the initial cooling. Accordingly, we find the Examiner's conclusion reasonable that "the temperature [of] the distal edge of the fin will always be higher than at the interior side of the wall, which means that heat must be transferred from the distal edge of the fin to the interior wall of the vessel when the biopharmaceutical [medium] is frozen and cannot move, because

by Fourier's Law of Heat Conduction, heat always flows from a high temperature location to a low temperature location" (page 15 of Final Rejection, last sentence). In our view, the Examiner has established a prima facie case that the Wisniewski system inherently allows for the formation of a thermal transfer bridge between the distal end of the structure and the interior wall of the container. We note that Wisniewski specifically discloses that "[t]he fin's length, thickness and shape were designed to maintain efficient heat transfer during freezing and thawing [and that] [o]ne important requirement is that the fins must be of sufficient thickness to allow adequate heat transfer by conduction towards the wall of the pipe" (page 387, last para.).

We concur with the Examiner that the Wisniewski Declarations offer little more than an unsupported opinion in which the declarant states, "[t]o the best of my knowledge," no thermal bridge is formed in the Wisniewski system because heat is not transferred from the fin through the medium to the interior wall. The declarant comes to the conclusion that "the temperature in the gap between the fin and the interior wall [in the Wisniewski system] increases and then decreases from the distal end of the fin to the interior wall ... because the gap between the distal end of the fin and the interior wall is too large" (page 3 of first Declaration, para. 8). However, as noted by the Examiner, the declarant cannot remember the distance between the distal end of the fin and the interior wall of the Wisniewski container. The declarant states "[a]though I cannot remember the exact distance between the fin tip and the interior wall of the Genentech [Wisniewski] device, I know that this distance was greater than 4 inches"

(second Declaration, page 2, para. 8). However, there is no evidence of record that a distance of greater than 4 inches, e.g., 4.1 inches, prevents the formation of a thermal transfer bridge between the fin and the interior wall of the container. For instance, Appellants' Specification provides no evidence that the distance must be less than 4 inches. Rather, Appellants' Specification states that the distance of the thermal bridge is a function of the thermal properties of the medium and the system and other relevant parameters and that "[t]he size of the gap to be filled by the bridge can be determined through simple trial and error, and the optimum gap may be no gap" (page 5 of Specification, ll. 7-8). The Specification further states that the "optimum gap is proportional to the thickness of the fin [and that] [i]n another aspect of the present invention, the optimum gap is less than 2 inches, preferably less than 1 inch, more preferably less than 1/2 inch, and even more preferably less than 1/4 inch, and most preferably less than 1/8 inch" (page 5, ll. 17-20). Hence, it can be seen that Appellants' Specification fails to provide evidence that a thermal bridge is not formed when the distance between the distal end of the fin and the interior wall of the container is 4 inches or greater. Manifestly, the disclosure of an *optimum* distance falls far short of a teaching that greater distances preclude the formation a thermal bridge.

In response to the Examiner's requirement that Appellants provide objective evidence that the Wisniewski system does not form a thermal bridge, Appellants lodge the following complaint:

> In fact, it is apparent that nothing short of actual experiments and/or computer analysis on all the prior art, including devices not in the possession or control of Appellant, would satisfy the

> Examiner. In fact, the Examiner goes as far as requiring Appellant contact a competitor/customer to ask for the dimensions of their device.

However, as noted by the Examiner, there is no evidence that Appellants have even attempted to acquire the dimensions of the system that Mr. Wisniewski's designed. Moreover, even assuming that Mr. Wisniewski's former employer would not cooperate with such a request, there is simply an utter lack of evidence that Appellants made any effort to recreate the Wisniewski system to the best of their knowledge and then ascertained that no thermal bridge is formed. Nor have Appellants established that a distance of 4 inches or greater between the distal end of the fin and the interior wall of the container necessarily precludes the formation of a thermal bridge between the distal end and the interior wall, regardless of the size and shape of the fin.

It is by now well settled that when a claimed system or process reasonably appears to be substantially the same as a system or process disclosed by the prior art, the burden is on the applicant to prove that the prior art system or process does not necessarily or inherently possess characteristics attributed to the claimed system or process. *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). In the present case, we find that the Examiner has made out a prima facie case that the system of Wisniewski reasonably appears to provide a thermal bridge between the distal end of the fin and the interior wall of the container. However, Appellants have not shouldered their burden of establishing that no thermal

bridge is formed in a system that is reasonably similar to the one disclosed by Wisniewski.

We now turn to the Examiner's § 103 rejections of the appealed claims. We are in full agreement with the Examiner that the "secondary" references clearly establish the obviousness of extending the fins of Wisniewski in closer proximity to the interior walls of the container "in order to advantageously increase the rate of heat transfer and "divide a tank volume into compartments to decrease the freezing [and] the thawing time and to reduce cryoconcentration effects" (1992 publication, page 136, col. 1, first full paragraph)" (Final Rejection, sentence bridging pages 19 and 20). It is clear from Wisniewski that the size of the fin is a result effective variable with respect to heat transfer from the fin through the medium, and the secondary references firmly establish that it was known in the art to extend heat transfer structures or fins in close proximity to the wall of a container. For example, the examiner points out that Morrison teaches than fins 7 span nearly the entire interior of the container to "ensure maximum heating or cooling surface, so that operation of the device may be carried out with facility" (col. 1, ll. 8-13).

It is also well settled that it is a matter of prima facie obviousness for one of ordinary skill in the art to determine the optimum value of a result effective variable through routine experimentation. *In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). In the present case, it is quite clear that it was well known in the art at the time of filing the present application that the size dimensions of heat transfer structures or fins of the type disclosed by Wisniewski are result effective variables which control the

heat transfer between the structure and the interior wall of the container. Accordingly, we are satisfied that the Examiner has drawn the proper legal conclusion that it would have been obvious for one of ordinary skill in the art to resort to routine experimentation to determine the optimum distance between the distal end of Wisniewski's fins and the interior wall of the container. Appellants have not proffered any objective evidence of unexpected results associated with the distances between the structure and the interior wall of the container that are within the scope of the appealed claims. As such, the Examiner's prima facie case of obviousness stands unrebutted.

We also concur with the Examiner that there does not appear to be a distinction between the thermal transfer systems of the admitted prior art, wherein the fins or structures within the container contact the interior wall of the container, and thermal transfer systems within the scope of the appealed claims. While Appellants maintain that the present invention does not contemplate "no gap" between the distal end of the fin and the interior wall of the container, Appellants' Specification states otherwise, specifically, that "the optimum gap may be no gap" (page 5 of Specification, line 8). The Examiner also cites page 11 of the Specification, lines 14-16. For sure, the reported optimum "no gap" would be the epitome of the claimed "close proximity." Neither Appellants' principal nor Reply Brief explains why the claim recitation "close proximity," when given its broadest reasonable interpretation in light of the Specification, does not embrace the optimum "no gap" disclosed in the Specification.

It conclusion, based on the foregoing and the reasons well stated by the Examiner, the Examiner's decision rejecting the appealed claims is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(iv)(effective Sept. 13, 2004).

AFFIRMED

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